Serial No.: 10/108,714 Nucleic Acid Encoding a Novel Human EP Prostaglandin Receptor

Filed: March 28, 2002

AMENDMENTS

Amendments to the Specification

1. Please replace the current title of the present specification with the following title:

NUCLEIC ACID ENCODING ANTIBODIES DIRECTED TOWARDS A NOVEL HUMAN EP PROSTAGLANDIN RECEPTOR

REMARKS

Amendments to the Specification

First, the Applicants thank the Examiner for pointing out the informalities contained within the specification. Specifically, the present specification was amended to change the title of the present specification. The Applicants hereby state that the amendment can find support in the present specification and does not add new subject matter.

Rejection Pursuant to 35 U.S.C. §112, ¶1 Enablement

The Examiner has rejected Claims 7-10 as allegedly lacking enablement under 35 U.S.C. §112, ¶1. Specifically, the Examiner suggests that plasmid KS/HP4, a biological material considered by the Examiner to be necessary for enablement of the present invention, was not made known and readily available to the public. The Applicants respectfully traverse this rejection and ask for reconsideration under 37 C.F.R. §1.111.

The Applicants respectfully point out to the Examiner that reference to this biological material is recited in the present specification on page 15, lines 14-17, "The below-referenced KS/HP4 plasmid has been deposited with the American Type Culture Collection and assigned Accession No. 97472." Therefore, the Applicants respectfully request withdrawal of the 35 U.S.C. §112, ¶1 enablement rejection for Claims 7-10.

Rejection Pursuant to 35 U.S.C. §102(b) and (e) Anticipation

The Examiner has rejected Claims 7-9 as allegedly anticipated under 35 U.S.C. §102(b) by Akiko Honda et al., *Cloning and Expression of a cDNA for Mouse Prostaglandin E Receptor EP₂ Subtype*, 268(11) J. BIOL. CHEM. 7759-7762 (1993) (hereafter "Honda publication"). Specifically, the Examiner holds that the mouse prostaglandin EP₂ receptor disclosed in the Honda publication anticipates the human HP4 receptor of the present specification because both proteins share a seven amino acid region of identity. The Applicants respectfully traverse this rejection and ask for reconsideration under 37 C.F.R. §1.111.

In citing case law, MPEP §2131 indicates that "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

The Applicants respectfully submit that the Examiner has failed to make a prima facie case of anticipation. The present invention claims an antibody composition that **specifically**

Serial No.: 10/108,714 Nucleic Acid Encoding a Novel Human EP Prostaglandin Receptor

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binds to the human prostaglandin HP4 receptor, or fragments thereof. By definition, an antibody which recognizes both the human HP4 receptor and the peptide disclosed in the Honda publication would not be "specific" to the HP4 receptor. Therefore, the Honda publication cannot anticipate the present claims. Furthermore, as pointed out by the Examiner, the Honda publication does not suggest or teach how to make or use antibodies to the human HP4 receptor at all, as it must do to anticipate the claimed invention; see, *e.g.*, pg. 3 "Honda do not teach antibodies." pg. 4 "Honda do not teach antibodies to this protein [the human prostaglandin HP4 receptor]." Therefore, the Applicants respectfully submit that the Honda publication cannot anticipate the present claims and respectfully request withdrawal of the 35 U.S.C. §102(b) anticipation rejection for Claims 7-9.

The Examiner has rejected Claims 7-10 as allegedly anticipated under 35 U.S.C. §102(e) by Mark Abramovitz et al., *DNA Encoding Prostaglandin Receptor IP*, U.S. Patent No. 5,516,652 (May 14, 1996) (hereafter "Abramovitz patent"). The Applicants respectfully traverse this rejection and ask for reconsideration under 37 C.F.R. §1.111.

The Abramovitz patent does not anticipate the present invention for the same rationale as discussed for the Honda publication. The Abramovitz patent does not disclose antibodies that **specifically** bind to polypeptide fragments comprising the human prostaglandin HP4 receptor. While the Abramovitz patent does disclose monoclonal antibodies to the human IP receptor, by definition, an antibody which recognizes both the human HP4 receptor and the human IP receptor would not be "specific" to the HP4 receptor. Therefore, the Applicants respectfully submit that the Abramovitz patent cannot anticipate the present claims and respectfully request withdrawal of the 35 U.S.C. §102(e) anticipation rejection for Claims 7-10.

Rejection Pursuant to 35 U.S.C. §103(a) Obviousness

The Examiner has rejected Claims 7-10 as allegedly being obvious under 35 U.S.C. §103(a) by the Honda publication in view of the Abramovitz patent. The Applicants respectfully traverse this rejection and ask for reconsideration under 37 C.F.R. §1.111.

In a rejection based on 35 U.S.C. 103, the reference teachings must somehow be modified in order to meet the claims. The modification must be one which would have been obvious to one of ordinary skill in the art at the time the invention was made. In addition, the Examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. As outlined in MPEP 2142, in order to establish a prima facie case of obviousness, three criteria must be met: 1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; 2) there must be a reasonable expectation of success; and 3) the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The Applicants respectfully submit that the Examiner has failed to make a prima facie case of obviousness. As already discussed above, the present application claims an antibody composition that specifically binds to the human prostaglandin HP4 receptor, or fragments thereof. The human prostaglandin HP4 receptor, its nucleic acid sequence and its amino acid sequence were not known until the present application was filed. Thus, it could not

Serial No.: 10/108,714 Nucleic Acid Encoding a Novel Human EP Prostaglandin Receptor

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have been possible for one of ordinary skill in the art to have envisioned an antibody that specifically recognizes the human HP receptor using the Honda publication in view of the Abramovitz patent. Therefore, the Honda publication and the Abramovitz patent, either alone or in combination, do not suggest or teach the antibody compositions claimed in the present application, and the Applicants respectfully submit that there is no obviousness and request withdrawal of the 35 U.S.C. §103(a) obvious rejection for Claims 7-10.

The Examiner has rejected Claims 7-10 as allegedly being obvious under 35 U.S.C. §103(a) by the Honda publication in view of the Dawn E. Colwell et al., *Method for Generating a High Frequency of Hybridomas Producing Monoclonal IgA Antibodies*, 121 METHODS ENZYMOL. 42-51 (1986) (hereafter "Colwell publication"). The Applicants respectfully traverse this rejection and ask for reconsideration under 37 C.F.R. §1.111.

The Applicant's respectfully submit that the Honda publication in view of the Colwell publication does not make the antibody composition claims of the present application obvious for the same rationale as described above. Because the human prostaglandin HP4 receptor, its nucleic acid sequence and its amino acid sequence were unknown until the present application was filed, it is not possible for the Honda publication in view of the Colwell publication to suggest or teach how to make antibodies that specifically bind to the human HP4 receptor to one of ordinary skill in the art. Therefore, the Honda and Colwell publications, either alone or in combination, do not suggest or teach the antibody compositions claimed in the present application, and the Applicants respectfully submit that there is no obviousness and request withdrawal of the 35 U.S.C. §103(a) obvious rejection for Claims 7-10.

CONCLUSION

In light of the amendments and remarks herein, the Applicants respectfully submit that the claims are now in condition for allowance and respectfully request the Examiner to issue a Notice to that effect. Should the Examiner have any questions, he is invited to call the undersigned agent. Please use Deposit Account 01-0885 for the payment of the extension fees or any other fees due in connection with the current response.

Respectfully submitted,

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Agent of Record



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